

amended claims 11 and 12 to overcome objections by the Examiner under 35 U.S.C. § 112 as described below. Applicants have also amended the specification to overcome objections to the specification as described below.

The Examiner has objected to the specification stating, "with respect to the amendment of the first line of the specification introduced in the First Preliminary Amendment of paper no. 5, applicants are referred to MPEP 1893.03(c), which states that 'a national stage application filed under 35 U.S.C. 371 may not claim benefit of the filing date of the international application of which it is the national stage since its filing date is the date of filing of that international application.' " In response, Applicants have amended the specification to reflect this.

In view of the foregoing, Appellants respectfully assert the Examiner's rejection cannot be sustained and should be withdrawn.

Further, the Examiner has requested that the paragraph be updated to state that application number 09/068,783 has now issued as Patent Number 6,337,185. In response, Applicants have amended the specification as the Examiner has suggested.

In view of the foregoing, Applicants respectfully assert the Examiner's rejection cannot be sustained and should be withdrawn.

The Examiner has objected to the title of the invention as not being descriptive of the invention. In response, Applicants have amended the title to be descriptive.

In view of the foregoing, Applicants respectfully assert the Examiner's rejection cannot be sustained and should be withdrawn.

The Examiner has rejected claims 11 and 12 under 35 U.S.C. § 112, second paragraph, as "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Specifically, the Examiner states, "claims 11-12 are indefinite over the recitation of the limitation 'both primers' in line 6 of claim 11. There is insufficient antecedent basis for this limitation in the claim."

In response, Applicants have amended claim 11 to recite that there are two amplification primers present. Applicants respectfully assert that there is sufficient basis in the Application for this amendment, and respectfully request it's entry,

In view of the foregoing, Applicants respectfully assert the Examiner's rejection cannot be sustained and should be withdrawn.

The Examiner has stated that "claim 12 is indefinite over the recitation of the language 'characterized in that.' " In response, Applicants have amended the Application to remove the objectionable language and replace with "wherein."

In view of the foregoing, Applicants respectfully assert the Examiner's rejections cannot be sustained and should be withdrawn.

The Examiner has rejected claims 11-12 under 35 U.S.C. § 102(b) as "being anticipated by Apple (W092/1 0589; 6/92)." Specifically, the Examiner states, "the claims are drawn to kits comprising a solid support, sequencing primers, and amplification primers comprising 'one member of a specific binding pair, the member being of the same type for both primers.' " The Examiner continues, "Apple teaches methods for amplifying and typing HLA DRbeta genes, and teaches kits comprising reagents that may be employed in his methods (p. 7-8; p. 45-50). Apple's kits comprise solid supports and primers which may be labeled or unlabeled (p. 7). Apple teaches the use of primer pairs wherein one or both primers are biotinylated (p. 34-37...); Apple therefore teaches primers that are 'differently labelled', as well as pairs of primers 'comprising one member of a specific binding pair' wherein the member is identical on each of the two primers in the pair."

The Examiner continues, "with respect to claim 12, Apple discloses the use of filters and a dot blot manifold (p. 25). With respect to the recitation in the claims of the language 'sequencing primers', the mere designation of primers as 'sequencing primers' does not further limit the primers with respect to structure or function; any primer may be employed in some manner in a method of sequencing. It is an inherent property of the primers of Apple that they could be employed in sequencing. Thus, Apple anticipates the

instant claims. It is also noted that Apple teaches that sequencing may be employed in analysis of HLA DRbeta genes (p. 7, p. 24)."

In response, Applicants respectfully disagree and respectfully submit the Examiner is misapplying the teachings of Apple. Specifically, Applicants concede that kits taught by the Apple reference comprise solid supports and primers; however, there is no disclosure, nor even any suggestion, of the inclusion of both amplification and sequencing primers as required in the claims of the instant applicant. Indeed, while there is a discussion of sequencing, the instant claims specifically require that both amplification and sequencing primers be present. Such is neither disclosed nor suggest by the Apple reference.

In view of the foregoing, Applicants respectfully assert the Examiner's rejections cannot be sustained and should be withdrawn.

The Examiner has rejected claim 11 under 35 U.S.C. § 102(b) as being "clearly anticipated by Soderland (EP 371437 A2; 6/90)." Specifically, the Examiner states, "the claim is drawn to a kit comprising a solid support, sequencing primers, and amplification primers comprising 'one member of a specific binding pair, the member being of the same type for both primers.' " The Examiner continues, "Soderland teaches methods for analysis of a nucleic acid sequence comprising PCR to produce a 'DNA sample in which at least one attachment moiety has been introduced into at least one strand of specific target polynucleotide', attachment of target to a 'solid matrix coated with an attachment

site to which the attachment moiety or a modification thereof can bind', and determination of the sequence of the amplified target by a method such as the chain termination method."

The Examiner further states, "the affinity pairs used for attachment of target to solid support may include 'biotin/avidin or streptavidin' and 'haptene/antibody' (col 5, lines 36-45). While Soderland states that, in embodiments employing two modified primers, 'The primers must in this case be modified with different attachment moieties', Soderland's teachings encompass the use of two different moieties that are 'of the same type' (e.g., two different haptens with two different antibodies) (col 5, lines 1-4). Soderland teaches that sequencing primers 'may be distinct from or equal to the primer used' in amplification, teaches the use of one or 'two different sequencing primers', and teaches a variety of different labels for use in sequencing primers, including fluorescent labels."

Continuing, the Examiner states, "Soderland discloses that 'Reagents for use in practising the method of invention may be packaged in kit form', including amplification primers with 'attachment moieties and the corresponding solid supports' and sequencing primers." The Examiner further states, "with respect to the language 'the member being of the same type for both primers', it is noted that Soderland teaches the use together of primers 'of the same type', as discussed above. Furthermore, even if claim 11 were limited to primers comprising identical binding pair members, Soderland would anticipate such kits; the claim as written encompasses inclusion of any number of

different primers, and is not limited to particular pairs of primers wherein both members of the pair comprise identical binding pair members.”

In response, Applicants respectfully submit the Examiner is mischaracterizing the teachings of Soderland. As the Examiner conceded, Soderland teaches that in embodiments employing two modified primers, the primers must be modified with different attachment moieties. Applicants respectfully assert that such is distinct from the instant claims, which recite that the member (of the specific binding pair) attached to the two amplification primers must be the “same type for both primers.” This member must be part of a specific binding pair permitting attachment to the support. Such is neither disclosed nor even suggested by the Soderland reference.

In view of the foregoing, Applicants respectfully assert the Examiner’s rejection cannot be sustained and should be withdrawn.

The Examiner has rejected claim 12 under 35 U.S.C. § 103(a) as “being unpatentable over Soderland (EP 371437 A2; 6/90) in view of Landegren (W094/1 1529; 5/94). Specifically, the Examiner states, “claim 12 is drawn to kits comprising a solid support which ‘is a manifold having a plurality of individual solid phase members’, differently labeled sequencing primers, and amplification primers comprising ‘one member of a specific binding pair, the member being of the same type for both primers.’ ” The Examiner continues, “Soderland teaches methods for analysis of a nucleic acid sequence comprising PCR to produce a ‘DNA sample in which at least one attachment

moiety has been introduced into at least one strand of specific target polynucleotide', attachment of target to a 'solid matrix coated with an attachment site to which the attachment moiety or a modification thereof can bind', and determination of the sequence of the amplified target by a method such as the chain termination method."

The Examiner states, "while Soderland teaches the use in his method and kits of a variety of different solid supports (microparticles, test tube, dipsticks, filters, microtitration wells), and states that 'the solid matrix can be of any format' (col 7, lines 4-20), Soderland does not disclose the use of a manifold 'having a plurality of individual solid phase members' as a solid support, or teach solid phase members 'adapted for cooperation with a corresponding set of receptacles', as required by the instant claim. Landegren teaches the use in nucleic acid sequencing of a solid support comprising a manifold..." The Examiner concludes, "in view of the teachings of Landegren, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Soderland so as to have included in Soderland's kits the manifold solid support of Landegren."

The Examiner further states, "with respect to the language 'the member being of the same type for both primers', it is again noted that Soderland teaches the use together of primers 'of the same type', as discussed above. Furthermore, even if claim 12 were limited to primers comprising identical binding pair members, the claimed kits would be obvious over the kits suggested by Soderland because the claim as written encompasses

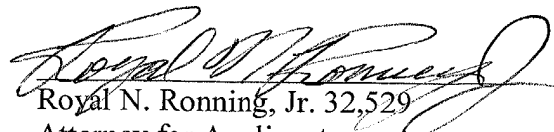
inclusion of any number of different primers, and is not limited to particular pairs of primers wherein both members of the pair comprise identical binding pair members."

In response, Applicant respectfully disagree with the Examiner and respectfully submit that the claims, as written, do require two amplification primers which comprise one member of a specific binding pair, the member being the same type for both primers. Such is neither disclosed nor even suggested by Landegren, which states that they must be different.

In view of this, Applicants respectfully assert that the above combination neither anticipates nor renders the instant invention obvious.

In view of the foregoing, Applicants respectfully assert the Examiner's rejection cannot be sustained and should be withdrawn. Applicants believe that the claims, as amended, are in allowable form and earnestly solicit the allowance of claims 11 and 12.


Respectfully submitted,

  
Royal N. Ronning, Jr. 32,529  
Attorney for Applicants

Amersham Biosciences Corp  
800 Centennial Avenue  
P. O. Box 1327  
Piscataway, New Jersey 08855-1327

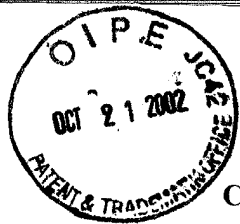
Tel: (732) 457-8423  
Fax: (732) 457-8463

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Melissa Leck  
Signature   
Date October 15, 2002

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Claims (marked up version showing amendments)

11. (once amended) A kit for use in analyzing the sequence of a polynucleotide of interest comprising:
  - (a) a solid support,
  - (b) two amplification primers comprising one member of a specific binding pair, the member being of the same type for both primers,
  - (c) sequencing primers.
  
12. (once amended) [A]The kit according to claim 11, [characterized in that]wherein the solid support is a manifold having a plurality of individual solid phase members and [that]wherein the sequencing primers are differently labelled.



Specification (marked up version showing amendments)

In the title:

“A Kit for Use in a Method of Sequencing”

The paragraph on page 1, line 1:

This application is a continuation of United States patent application serial number 09/068,783[ having a filing date of February 22, 1999], which is a national stage filing under 35 U.S.C. 371 claiming priority to international patent application number PCT/SE96/01464, filed November 13, 1996, the entire disclosure of which is incorporated herein by reference, now issued as United States Patent Number 6,337,185.